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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,587	03/29/2004	Daniele Pressato	2039-0124PUS2	2626
2292 7590 06/18/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER MAIER, LEIGH C	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 06/18/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

## Office Action Summary

Application No.

10/812,587

Applicant(s)

PRESSATO ET AL.

Examiner

Leigh C. Maier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-25 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 15-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 27, 2007 has been entered.

Claims 1-10 have been canceled. Claims 11, 16, 19-21, 22 and 23 have been amended. Claim 25 is newly submitted. Claims 11-25 are pending. Claims 12-14 are currently withdrawn as being drawn to a non-elected species. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any rejection or objection not expressly repeated has been withdrawn.

### ***Claim Rejections - 35 USC § 112***

Claims 11 and 15-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims describe the viscosity of the product used in the units of "Pa\*sec<sup>-1</sup>". The examiner does not find this to be a standard unit used in the art to measure viscosity. Therefore one of ordinary skill would not be apprised of the metes and bounds of the claim. If this unit of

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measure is maintained, Applicant is required to provide documentation as to how this unit of measure converts to more standard measures used in the art.

***Claim Rejections - 35 USC § 103***

Claims 11, 16, and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (EP 341745) in view of Malson et al (US 5,783,691) and Huang et al (US 5,532,221).

Della Valle teaches autocrosslinked HA, with a 5% crosslinked product exemplified. See abstract and examples 2 and 3. The reference further teaches the use of this product in a variety of forms, such as films, sheets and threads. See page 11, lines 10-20. The reference further states that the articles prepared using the HA products are "similar to those already known and commercially available or described in the literature," thereby specifically suggesting the use of this product in place of other similar products known in the art. The reference is silent regarding the prevention of surgical adhesions, but the use of crosslinked HA for this purpose is known generally in the art.

Malson teaches that HA and (covalently) crosslinked HA derivatives are known generally to be useful in medical applications, such as prevention of post-operative adhesions. See col 1, lines 19-54. The reference is drawn specifically to HA that is crosslinked through phosphate ester linkages. See col 1, lines 55-62. The reference further teaches the use of this product as a slow-release form of HA, useful for the applications known for HA, per se, and other crosslinked HA derivatives. See col 4, lines 10-39. Finally, the reference teaches that this product is superior

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to other known crosslinked HAs because it introduces fewer “alien” products that may result in immunological or inflammatory reactions. See col 1, lines 43-54.

Huang teaches the use of (ionically) crosslinked HA for the prevention of surgical adhesions. The reference teaches the administration of the product in a variety of surgical procedures and in combination with a number of anti-adhesion therapeutic agents. See col 3-4 and col 5, lines 1-8. The reference further teaches that the efficacy of the product in preventing adhesions is a function of the viscosity and degree of crosslinking.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the Della Valle crosslinked HA products for the prevention of post-surgical adhesions. One of ordinary skill would reasonably expect success in using this product for such prevention because Malson and Huang had taught that HA and crosslinked HA derivatives are known to have this utility. The artisan would be further motivated to use this product because it is crosslinked without incorporating into the covalent structure chemicals that could produce undesirable immunological/inflammatory reactions. In the absence of unexpected results, it would further be within the scope of the artisan to prepare and administer the crosslinked HA in any form useful in surgery. It is noted that the examiner finds no definition of “membrane” that would distinguish it from “film” or “sheet.”

Regarding the types of surgery, the references teach that the problem of adhesion formation is a problem in surgery generally, with Huang teaching a few species. However, claim 24 appears to cover essentially any type of surgery that might be contemplated by one of ordinary skill and would be essentially the same as reciting surgery per se. In the absence of unexpected results with a particular type of surgery, it would be within the scope of the artisan to

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administer this product in any type of surgery as indicated with a reasonable expectation of success.

Regarding the limitations viscosity, degree of crosslinking and molecular weight, as discussed above, Huang had taught that the efficacy of the product is a function of viscosity and degree of crosslinking. Della Valle had taught the preparation of crosslinked products with 5% being exemplified. Viscosity is a function of molecular weight and concentration. Therefore, the art teaches how to prepare a product for optimal anti-adhesion properties. It would be within the scope of the artisan to optimize these variables through routine experimentation with a reasonable expectation of success. Applicant has pointed to the data disclosed in the specification showing that the ability of the product to prevent adhesions increases with viscosity as unexpected results. However, this is exactly consistent with what is known in the art and does not appear to be unexpected.

Applicant further argues that not all HA derivatives and crosslinked derivatives are useful for each and every purpose, and this is borne out by the data in Study 8. This data demonstrates that a product having low viscosity has lesser efficacy than a product with higher viscosity. However, as discussed above, it is known in the art that viscosity is a critical parameter in the ability of a product to have utility as an anti-adhesive agent. The examiner maintains that one of ordinary skill would reasonably expect based on what is known in the art that the Della Valle product, with appropriate viscosity and crosslinking, would be useful as an anti-adhesive agent.

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Claims 11, 16, and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (EP 341745) in view of Malson et al (US 5,783,691) and Huang and further in view of Matsuda et al (US 5,462,976).

Della Valle, Malson and Huang teach as set forth above. The references do not teach the full range of forms recited in claim 19.

Matsuda also teaches that crosslinked glycosaminoglycans, such as HA, have are useful for the prevention of surgical adhesions. See section bridging col 17-18 and examples 19 and 25. The reference further teaches that these crosslinked biopolymers may be prepared in a variety of forms, such as knit, woven or non-woven fabrics, etc. See col 18, lines 45-62.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the Della Valle crosslinked HA material in any form known to be useful for surgical applications with a reasonable expectation of success. Della Valle had specifically taught the preparation of crosslinked HA in the form of threads. In the absence of unexpected results, it would be within the scope of the artisan to further process such threads and prepare the product in the forms suggested by Matsuda.

LCM  
11 and 15-25  
Claims ~~11-25~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al (EP 341745) in view of Malson et al (US 5,783,691) and Huang et al (US 5,532,221) and further in view of Dorigatti et al (WO 94/17837).

Della Valle, Malson and Huang teach as set forth above. The references do not teach the use of a biomaterial comprising a non-biodegradable synthetic polymer.

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Dorigatti teaches the use of a HA derivative in combination with various synthetic polymers. This material has utility as an anti-adhesive product for use in surgery. See abstract; page 7, lines 6-28; examples; and reference claim 36.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the product disclosed by Dorigatti by the use of the HA product disclosed by Della Valle. As discussed previously, HA products are known generally to have anti-adhesive properties. Therefore, one of ordinary skill would reasonably expect success in preparing a multilayer product taught by Dorigatti using the Della Valle crosslinked HA.

***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Monday, Tuesday and Thursday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

*Leigh C. Maier*

Leigh C. Maier  
Primary Examiner  
June 11, 2007